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09/749,152	12/27/2000	Peter Watts	10774-21U1	5106

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EXAMINER	
TRAN, SUSAN T	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 01/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/749,152	WATTS, PETER	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *4,7,11,13-16 and 19-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,6,8-10,12,17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Election filed 10/14/04.

Election/Restrictions

Applicant's election with traverse of Group III (claim 6), and specie e (budesonide) in the reply filed on 10/14/04 is acknowledged. The traversal is on the ground(s) that this application is a continuing application claiming priority to US application No. 08/765,347 ('347). The '347 application is a national state application filed under 35 U.S.C. § 371; however, a continuation application claiming priority to a national stage application is not a national stage application, therefore, restriction practice under 35 U.S.C. § 121 is applicable and not the unity of invention standard. In response to applicant's argument, the examiner agreed that the restriction should practice under 35 U.S.C. § 121, and under this legal standard, the restriction requirement dated 0910/04 is still applicable because coating polymers in the four group are different, both, in structures and properties. As stated in the restriction requirement, "the structures differ from each of the inventions are the coating polymers put on the capsule. Although they might have common unity, there is no common structure" (distinct).

The requirement is still deemed proper and is therefore made FINAL.

Claims 4, 7, 11, 13-16 and 19-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species,

there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/14/04.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5, 6, 8-10, 12, 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor at the time the application was filed, had possession of the claimed invention. It appears that applicant's specification does not explicitly provide support for the limitation "[coating] that covers the entire capsule". Applicant's attention is called to specification at page 4, lines 25-27 discloses "[the capsules] comprise two components, a body and a cap. The body is filled with the drug to be delivered and the cap is then attached and sealed". However, nowhere in the specification explicitly discloses that both, the body and the cap are coated entirely.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Rashid et al. WO 94/09745.

Rashid discloses a controlled release capsule comprising starch capsule coated with a solution of polyvinyl chloride or a polyvinyl acetate copolymer (page 7, 1st paragraph). Rashid further teaches the capsule is filled with pharmaceutical active agent, and after 2 to 10 hours of administration, the active agent is released into the patient's gastro-intestinal tract (pages 10-11).

Claims 1-3, 5, 6, 9, 10 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Dansereau et al. US 5,622,721.

Dansereau discloses an enteric-coated oral dosage form, wherein the release of active agent is to the lower gastrointestinal tract (see abstract, column 2, lines 50-65).

The dosage form can be an enteric-coated starch or gelatin capsule (column 6, lines 52 through column 7, lines 1-10). The coating includes, polymer or copolymer that dissolves at a pH of 5.5 or above, *e.g.*, Eudragit®, or methacrylic acid polymer-copolymer (columns 9-10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5, 6, 8-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhodes et al. WO 92/14452, in view of Dansereau et al. US 5,622,721 and Sintov et al. US 5,525,634.

Rhodes discloses a delayed release oral dosage form for treatment of colonic disorders, the dosage form comprising plurality of granules of the drug contained in a coated capsule, wherein the drug granules and the capsule are coated with the same or different coating material (see abstract, page 1, lines 4-10, and page 9, lines 23-27). The capsule can be soft or hard gelatin capsule, and the enteric coating materials are selected from Eudragit range of (meth)acrylate and (meth)acrylic acid polymer (see abstract, page 13, lines 24 through page 14, lines 1-16). Drug includes topically active drug to the intestine, such as topically active steroid (page 11, lines 1-15).

Rhodes does not expressly teach the starch capsule.

Dansereau teaches an enteric-coated oral dosage form, wherein the release of active agent is to the lower gastrointestinal tract (see abstract, column 2, lines 50-65). The dosage form is in an enteric-coated starch or gelatin capsule (column 6, lines 52 through column 7, lines 1-10). The coating includes, polymer or copolymer that dissolves at a pH of 5.5 or above, *e.g.*, Eudragit®, or methacrylic acid polymer-copolymer (columns 9-10). Thus, it would have been obvious for one of ordinary skill in the art to modify the enterically coated capsule of Rhodes using the starch capsule in view of the teachings of Dansereau, because Rhodes teaches the use of other capsule which will dissolved in the small intestine (page 13, lines 24-26), because Dansereau teaches a delayed release dosage form suitable to deliver drug to the large intestine (including colon) (column 7, lines 11-32), and because Dansereau teaches an enterically coated capsule desired to effect the topical delivery via the oral administration.

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhodes et al. WO 92/14452, in view of Dansereau et al. US 5,622,721 and Sintov et al. US 5,525,634.

Rhodes and Dansereau are relied upon for the reasons stated above. The references do not expressly teach budesonide as an active agent.

Sintov teaches a colonic delivery system for delivering a drug to the colon for the treatment of colonic disease (see abstract). Desired drug to the colon includes steroid drugs such as budesonide (column 7, lines 4-15). Sintov further teaches colonic

disease includes irritable bowel disease, ulcerative colitis, or colon carcinoma (Crohn's disease) (column 7, lines 22-35). Thus, it would have been obvious for one of ordinary skill in the art to modify the enteric-coated capsule of Rhodes in view of Dansereau for the delivery of budesonide in view of the teaching of Sintov, because Sintov teach a similar colonic delivery system for delivering a drug to the colon using similar drug, such as steroid for the treatment of colonic disorder.

Claims 1-3, 5, 6, 8-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. US 5,670,158, and McNeil et al. US 5,342,624.

Davis teaches pharmaceutical dosage form for colonic delivery comprising drug encapsulated in an enteric-coated capsule (column 6, lines 27-48). The enteric coating comprises pH sensitive material that will dissolve at a pH of above 5, *e.g.*, polymethacrylates (column 9, lines 1-11). Davis does not teach the claimed starch capsule.

McNeill teaches hard gelatin capsule or starch capsule are conventional class of capsules (column 6, lines 10-25). Hence, it is the examiner's position that gelatin capsule and starch capsule are substantially equivalent, and therefore, it would have been obvious for one of ordinary skill in the art to modify Davis' capsule using the starch capsule, because the references teach the advantageous results in the use of a controlled release device useful to deliver drug to the colon. The expected result would be an enteric-coated starch capsule suitable for colonic delivery to treat colonic diseases

The examiner notes that the references do not teach the coating thickness as defined in claim 8. However, Davis teaches the thickness of the coating depends in the desired rate of dissolution and the site of release. Therefore, it is the position of the examiner that it would have been obvious to one skilled in the art to manipulate the coating thickness similar to that of the claimed coating thickness, because the references also desired to release the active agent in the colon.

Claims 1-3, 5, 6, 8-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. US 5,670,158, in view of Digenis et al. US 5,672,359.

Davis is relied upon for the reason stated above. Davis does not teach the claimed starch capsule.

Digenis teaches coated hard gelatin capsule made from gelatin or starch or hydrophilic polymer suitable for colonic delivery of peptide drugs (column 4, lines 20-67, column 8, lines 50-57, and examples). Thus, it would have been obvious for one of ordinary skill in the art to optimize Davis' capsule using the starch capsule in view of the teaching of Digenis, since Digenis teaches that hard gelatin capsule can be gelatin or starch or hydrophilic. The expected result would be a coated capsule useful for colonic delivery.

The examiner notes that the references do not teach the coating thickness as claimed in claim 8. However, Dansereau teaches the coating also achieves the delivery to the active to the lower gastrointestinal tract at a point which can be manipulated by

one skilled in the art by choosing the excipients which make up the coating, its type, and/or its thickness. In additionally, Rhodes teaches that it is well within the ability of one of ordinary skill in the art to determine by trial-and-error experimentation the optimum thickness of a coating required for a particular dosage form with the expectation to deliver the drug to the desired cited. Accordingly, it is the position of the examiner that it would have been obvious for one of ordinary skill in this art to, by routine experimentation determines a suitable thickness for the coating to obtain a desirable release of active agent in a colon.

Response to Arguments

Applicant's arguments filed 05/19/04 have been fully considered but they are not persuasive.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Rashid et al. WO 94/09745.

Applicant argues that Rashid does not provide a teaching of a capsule that is (1) *entirely* formed of starch, and (2) coated throughout with a coating that covers the entire capsule. In response to applicant's argument, it is noted that the limitation "capsule that is entirely formed of starch" is not recited in the rejected claim. Although the claim is interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Regarding the limitation coated throughout with a coating that covers the entire capsule, it appears that applicant's specification does not explicitly support said limitation.

Applicant's capsule is also a two-piece capsule comprises a cap and a body (see page 4, lines 25-27), however, nowhere in the specification explicitly discloses that both, the body and the cap are coated entirely.

Claims 1, 2, 5, 6, 9, 10 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Dansereau et al. US 5,622,721.

Applicant argues that Dansereau describes enteric-coated starch capsules that also contain coated beads, granules or particles. Thus, the teachings of Dansereau suggest that the coating of the starch capsules alone is not sufficient to ensure that the drug is predominantly released in the colon or terminal ileum as required by the invention. Compositions in which only the capsule is enteric coated. Contrary to the applicant's argument, there's nothing in the rejected claims require that the drug cannot be coated. The phrase "[A] drug delivery composition…comprising a starch capsule containing the drug" permits "the drug" to be in any form, including coated beads, granules or particles as discloses in Dansereau. Furthermore, applicant's attention is called to column 6, lines 49-51, where Dansereau discloses the beads or granules of the active agent can be coated or *uncoated*.

Applicant argues that the enteric coating as described by Dansereau is not the same as the claimed coating such that the drug is predominantly released in the terminal ileum or colon. Contrary to the applicant's argument, it is noted that Dansereau used the same coating polymer or copolymer that dissolves at a pH of 5.5 or above, *e.g.*, Eudragit®, or methacrylic acid polymer-copolymer (columns 9-10), as well as the same region where drug is to be released. It is noted that products of identical chemical

composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) Accordingly, Dansereau does teach the claimed coating.

Claims 1-3, 5, 6, 8-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. US 5,670,158, and McNeil et al. US 5,342,624.

Applicant argues that McNeil does not cure the deficiencies of Davis. Applicant alleges that there is no teaching in McNeil that the entire device bears a coating. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). As discus above, applicant's specification has not provided any explicit support that the capsule of the claimed invention is entirely covered by a coating. Similarly, the disclosure of McNeil can be interpreted as the entire capsule is coated, or partially coated. Nonetheless, McNeil is relied upon solely for the teaching of the *conventional class of capsule includes starch capsule*.

Claims 1-3, 5, 6, 8-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. US 5,670,158, in view of Digenis et al. US 5,672,359.

Applicant argues that a person of skill in the art would not have been motivated to combine the teachings of Davis with those of Digenis, which are directed to a step-wise delivery of three or more drugs over a period of time from seconds to hours. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Digenis is relied upon solely for the teaching of hard gelatin capsule is capsule made from gelatin or starch or hydrophilic polymer suitable for colonic delivery of drugs.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Busetti et al., and Berliner et al. are cited as of interest for the teachings of colonic delivery systems.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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